
Rules of
Department of Health
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

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**Title 19—DEPARTMENT OF
HEALTH**

**Division 30—Division of
Health Standards and Licensure
Chapter 1—Controlled Substances**

**19 CSR 30-1.010 Schedules of Controlled
Substances**

PURPOSE: Chapter 195, RSMo states in section 195.230, RSMo that the Department of Health shall prepare a list of all drugs falling within the purview of controlled substances. Upon preparation, a copy of the list shall be filed in the Office of the Secretary of State. It also requires, in section 195.017.11, RSMo, the Department of Health to revise and republish the schedules semiannually for two years from September 28, 1971, and annually after that.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) Schedules of Controlled Substances.

(A) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the Drug Enforcement Administration (DEA) Controlled Substances Code Number set forth opposite it.

1. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

A. Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidinyl)-N-phenylacetamide)	9815
B. Acetylmehtadol	9601
C. Allylprodine	9602
D. Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol levo-thadyl acetate or LAAM)	9603
E. Alphameprodine	9604
F. Alphamethadol	9605

G. Alpha-methylfentanyl (N-1-(alphamethyl-beta-phenyl)ethyl-4-piperidyl) propionanilide; 1-(1-methyl-2-phenylethyl)-4((N-propanilido) piperidine)	9814
H. Alpha-methylthiofentanyl (N-(1-methyl-2-(2-thienyl)ethyl-4-piperidinyl)-N-phenylpropanamide)	9832
I. Benzethidine	9606
J. Betacetylmethadol	9607
K. Beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenethyl)-4-piperidinyl)-N-phenylpropanamide)	9830
L. Beta-hydroxy-3-methylfentanyl (other name: N-(1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl)-N-phenylpropanamide)	9831
M. Betameprodine	9608
N. Betamethadol	9609
O. Betaprodine	9611
P. Clonitazene	9612
Q. Dextromoramide	9613
R. Diampromide	9615
S. Diethylthiambutene	9616
T. Difenoxin	9168
U. Dimenoxadol	9617
V. Dimepheptanol	9618
W. Dimethylthiambutene	9619
X. Dioxaphetyl butyrate	9621
Y. Dipipanone	9622
Z. Ethylmethylthiambutene	9623
AA. Etonitazene	9624
BB. Etoxeridine	9625
CC. Furethidine	9626
DD. Hydroxypethidine	9627
EE. Ketobemidone	9628
FF. Levomoramide	9629
GG. Levophenacetyl morphan	9631
HH. 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-piperidyl)-N-phenylpropanamide), its optical and geometric isomers, salts and salts of isomers	9813
II. Morpherdine	9632
JJ. 3-Methylthiofentanyl (N-(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl)-N-phenylpropanamide)	9833
KK. MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)	9661
LL. Noracymethadol	9633
MM. Norlevorphanol	9634
NN. Normethadone	9635
OO. Norpipanone	9636
PP. PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine)	9663

QQ. Para-fluorofentanyl (N-(4-fluorophenyl)-N-(1-(2-phenethyl)-4-piperidinyl) propanamide)	9812
RR. Phenadoxone	9637
SS. Phenampromide	9638
TT. Phenomorphan	9647
UU. Phenoperidine	9641
VV. Piritramide	9642
WW. Proheptazine	9643
XX. Properidine	9644
YY. Propiram	9649
ZZ. Racemoramide	9645
AAA. Tilidine	9750
BBB. Thiofentanyl (N-phenyl-N-(1-(2-thienyl)ethyl-4-piperidinyl)-propanamide)	9835
CCC. Trimeperidine	9646
2. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:	
A. Acetorphine	9319
B. Acetyldihydrocodeine	9051
C. Benzylmorphine	9052
D. Codeine methylbromide	9070
E. Codeine-N-Oxide	9053
F. Cyprenorphine	9054
G. Desomorphine	9055
H. Dihydromorphine	9145
I. Drotebanol	9335
J. Etorphine (except hydrochloride salt)	9056
K. Heroin	9200
L. Hydromorphanol	9301
M. Methyl-desorphine	9302
N. Methyl-dihydromorphine	9304
O. Morphine methylbromide	9305
P. Morphine methylsulfonate	9306
Q. Morphine-N-Oxide	9307
R. Myrophine	9308
S. Nicocodeine	9309
T. Nicomorphine	9312
U. Normorphine	9313
V. Pholcodeine	9314
W. Thebacon	9315
3. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances or which contains any of its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation (For purposes of paragraph (1)(A)3. of this rule only, the term isomer includes the optical, position and geometric isomers.):	

A. 4-bromo-2,5-dimethoxyamphetamine 7391
Some trade or other names: 4-bromo-2, 5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA;

B. 2,5-dimethoxyamphetamine 7396
Some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA;

C. 2,5-dimethoxy-4-ethylamphetamine 7399
(Some trade or other names: DOET) 7399

D. 4-methoxyamphetamine 7411
Some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA;

E. 5-methoxy-3,4-methylenedioxyamphetamine 7401

F. 4-methyl-2,5-dimethoxyamphetamine 7395
Some trade and other names: 4-methyl-2, 5-dimethoxy-a-methylphenethylamine; DOM; and STP;

G. 3,4-methylenedioxy amphetamine 7400

H. 3,4-methylenedioxymethamphetamine (MDMA) 7405

I. 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy) phenethylamine, N-ethyl MDA, MDE and MDEA) 7404

J. N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4-(methylenedioxy) phenethylamine and N-hydroxy MDA) 7402

K. 3,4,5-trimethoxy amphetamine 7390

L. Bufotenine 7433
Some trade and other names: 3-β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;

M. Diethyltryptamine 7434
Some trade and other names: N, N-Diethyltryptamine; DET;

N. Dimethyltryptamine 7435
Some trade or other names: DMT;

O. Ibogaine 7260
Some trade and other names: 7-Ethyl-6,6β,7,8,9,10,12,13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5, 4-b) indole; Tabernanthe iboga;

P. Lysergic acid diethylamide 7315

Q. Marihuana 7360

R. Mescaline 7381

S. Parahexyl 7374
Some trade or other names: 3-Hexyl-1-Hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo(b,d)pyran; Synhexyl;

T. Peyote 7415
Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* *Lemaire*, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or extracts;

U. N-ethyl-3-piperidyl benzilate 7482

V. N-methyl-3-piperidyl benzilate 7484

W. Psilocybin 7437

X. Psilocyn 7438

Y. Tetrahydrocannabinols 7370
Synthetic equivalents of the substances contained in the plant or in the resinous extracts of *Cannabis*, sp, synthetic substances, derivatives and their isomers, or both, with similar chemical structure and pharmacological activity such as the following:
(I) Δ 1 cis or trans tetrahydrocannabinol and their optical isomers;
(II) Δ 6 cis or trans tetrahydrocannabinol and their optical isomers; and
(III) Δ 3, 4 cis or trans tetrahydrocannabinol and its optical isomers (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.);

Z. Ethylamine analog of phenicyclidine 7455
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl)-ethylamine, cyclohexamine, PCE;

AA. Pyrrolidine analog of phenicyclidine 7458
Some trade or other names: 1(1-phenylcyclohexyl)-pyrrolidine PCPy, PHP;

BB. Thiophene analog of phenicyclidine 7470
Some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine, 2-thienyl analog of phenicyclidine, TPCP, TCP.

CC. 1-(1-(2-thienyl)cyclohexyl) pyrrolidine 7473
Some other names: TCPy; and

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:
A. Mecloqualone 2572
B. Methaqualone 2565

5. Stimulants. Unless specifically excepted or unless listed in another schedule,

any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:
A. Cathinone (Some trade or other names: 2-amino-1-phenyl-1-propanone, alphaaminopropiophenone, 2-aminopropiophenone and norephedrone) 1235

B. Fenethylline 1503

C. (±)cis-4-methylaminorex ((±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) 1590

D. N-ethylamphetamine 1475

E. N,N-dimethylamphetamine (some other names: N,N-alpha-trimethylbenzeneethanamine; N,N-alpha-trimethylphenethylamine), its salts, optical isomers and salts of optical isomers 1480

6. A temporary listing of substances subject to emergency scheduling under federal law shall include any material, compound, mixture or preparation which contains any quantity of the following substances:
A. N-(1-benzyl-4-piperidyl)-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers 9818

B. N-(1-(2-thienyl) methyl-4-piperidyl)-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers 9834

C. Methcathinone (Some other names: 2-methylamino-1-phenylpropan-1-one; ephedrone; monomethylpropion UR 1431, its salts, optical isomers and salts of optical isomers) 1237

D. Aminorex (Some other names: aminoxaphen, 2-amino-5-phenyl-2-oxazoline or 4,5-dihydro-5-phenyl-2-oxazolamine, its salts, optical isomers and salts of optical isomers) 1585

E. Alpha-ethyltryptamine, its optical isomers, salts and salts of isomers (Some other names: etryptamine; Alphaethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole) 7249

(B) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.
1. Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, Schedule II

shall include any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis opium and opiate; and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone and their respective salts, but including the following:

A. Raw opium	9600
B. Opium extracts	9610
C. Opium fluid	9620
D. Powdered opium	9639
E. Granulated opium	9640
F. Tincture of opium	9630
G. Codeine	9050
H. Ethylmorphine	9190
I. Etorphine hydrochloride	9059
J. Hydrocodone	9193
K. Hydromorphone	9150
L. Metopon	9260
M. Morphine	9300
N. Oxycodone	9143
O. Oxymorphone	9652
P. Thebaine	9333

Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1)(B)1. of this rule shall be included in Schedule II, except that these substances shall not include the isoquinoline alkaloids of opium; opium poppy and poppy straw; coca leaves 9040 and any salt, compound, derivative or preparation of coca leaves including cocaine 9041 and ecgonine 9180 and their salts, isomers, derivatives and salts of isomers and derivatives and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine 9041 or ecgonine 9180

and concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy) 9670

2. Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

A. Alfentanil	9737
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B. Alphaprodine	9010
C. Anileridine	9020
D. Bezitramide	9800
E. Bulk Dextropoxyphene (Non-dosage Forms)	9273
F. Butyl-nitrite	no designated number
G. Carfentanil	9743
H. Dihydrocodeine	9120
I. Diphenoxylate	9170
J. Fentanyl	9801
K. Isomethadone	9226
L. Levo-alphaacetylmethadol (Some other names: levo-alphaacetylmethadol, levomethadyl acetate, LAAM)	9648
M. Levomethorphan	9210
N. Levorphanol	9220
O. Metazocine	9240
P. Methadone	9250
Q. Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenylbutane	9254
R. Moramide-Intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid	9802
S. Pethidine (Meperidine)	9230
T. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
U. Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
V. Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
W. Phenazocine	9715
X. Piminodine	9730
Y. Racemethorphan	9732
Z. Racemorphan	9733
AA. Sufentanil	9740

3. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

A. Amphetamine, its salts, optical isomers and salts of its optical isomers	1100
B. Methamphetamine, its salts, isomers and salts of its isomers	1105
C. Phenmetrazine and its salts	1631
D. Methylphenidate	1724

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts

of isomers is possible within the specific chemical designation:

A. Amobarbital	2125
B. Glutethimide	2550
C. Pentobarbital	2270
D. Phencyclidine	7471
E. Secobarbital	2315

5. Hallucinogenic substances:

A. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product 7369

(Some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6.6.9-trimethyl-3-pentyl-6H-dibenzo (b,d) pyran-1-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.); and

B. Nabilone	7379
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(Another name for nabilone: (\pm)trans-3-(1,1-dimethylheptyl)-6, 6a,7,8,10,10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo (b,d) pyran-9-one.)

6. Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

A. Immediate precursor to amphetamine and methamphetamine:

(I) Phenylacetone	8501
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Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

B. Immediate precursors to phencyclidine (PCP):

(I) 1-phenylcyclohexylamine	7460
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(II) 1-piperidinocyclohexane-carbonitrile (PCC)	8603
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(C) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Those compounds, mixtures or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures or preparations were listed on August 25, 1971, as excepted compounds under section 308.32 and any other drug of the quantitative composition

shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances

- B. Benzphetamine 1228
- C. Chlorphentermine 1645
- D. Clortermine 1647
- E. Phendimetrazine 1615

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

A. Any compound, mixture or preparation containing:

- (I) Amobarbital 2126
- (II) Secobarbital 2316
- (III) Pentobarbital 2271

or any salt thereof and one (1) or more other active medicinal ingredients which are not listed in any schedule;

B. Any suppository dosage form containing:

- (I) Amobarbital 2126
- (II) Secobarbital 2316
- (III) Pentobarbital 2271

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

C. Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof 2100

- D. Chlorexadol 2510
- E. Lysergic acid 7300
- F. Lysergic acid amide 7310
- G. Methyprylon 2575
- H. Sulfondiethylmethane 2600
- I. Sulfonethylmethane 2605
- J. Sulfonmethane 2610

K. Tiletamine and zolazepam or any salt thereof 7295

Some trade or other names for a tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6-8-dihydro-1,3,8-trimethylpyrazolo-(3,4-e) (1,4)-diazepin-7(1H)-one, flupyrazopon.

3. Nalorphine 9400

4. Narcotics drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than 1.8 grams of codeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803

B. Not more than 1.8 grams of codeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804

C. Not more than three hundred milligrams (300 mg) of dihydrocodeinone per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium 9805

D. Not more than three hundred milligrams (300 mg) of dihydrocodeinone per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts 9806

E. Not more than 1.8 grams of dihydrocodeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9807

F. Not more than three hundred milligrams (300 mg) of ethylmorphine per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

G. Not more than five hundred milligrams (500 mg) of opium per one hundred milliliters (100 ml) or per one hundred grams (100 g) or not more than twenty-five milligrams (25 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts 9809

H. Not more than fifty milligrams (50 mg) of morphine per one hundred milliliters (100 ml) or per one hundred grams (100 g), with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810

5. Anabolic steroids. Unless specially excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation. DEA has assigned code 4000 for all anabolic steroids.

- A. Boldenone
- B. Chlorotestosterone (4-Chlortestosterone)
- C. Clostebol
- D. Dehydrochlormethyltestosterone
- E. Dihydrotestosterone (4-Dihydrotestosterone)
- F. Drostanolone

- G. Ethylestrenol
- H. Fluoxymesterone
- I. Formebolone (Formebolone)
- J. Mesterolone
- K. Methandienone
- L. Methandranone
- M. Methandriol
- N. Methandrostenolone
- O. Methenolone
- P. Methyltestosterone
- Q. Mibolerone
- R. Nandrolone
- S. Norethandrolone
- T. Oxandrolone
- U. Oxymesterone
- V. Oxymetholone
- W. Stanolone
- X. Stanozolol
- Y. Testolactone
- Z. Testosterone

AA. Trenbolone

BB. Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph, if that salt, ester or isomer promotes muscle growth except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of Health and Human Services for that administration.

(D) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

- A. Not more than one milligram (1 mg) of difenoxin (DEA Drug Code No. 9618) and not less than twenty-five micrograms (25 µg) of atropine sulfate per dosage unit;
- B. Dextropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) 9278

C. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(I) Not more than two hundred milligrams (200 mg) of codeine per one hundred milliliters (100 ml) or per one hundred grams (100 g);

(II) Not more than one hundred milligrams (100 mg) of dihydrocodeine per one hundred milliliters (100 ml) or per one hundred grams (100 g); or

(III) Not more than one hundred milligrams (100 mg) of ethylmorphine per one hundred milliliters (100 ml) or per one hundred grams (100 g).

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Alprazolam	2882
B. Barbitol	2145
C. Bromazepam	2748
D. Camazepam	2749
E. Chloral betaine	2460
F. Chloral hydrate	2465
G. Chlordiazepoxide	2744
H. Clobazam	2751
I. Clonazepam	2737
J. Clorazepate	2768
K. Clotiazepam	2752
L. Cloxazolam	2753
M. Delorazepam	2754
N. Diazepam	2765
O. Estazolam	2756
P. Ethchlorvynol	2540
Q. Ethinamate	2545
R. Ethyl loflazepate	2758
S. Fludiazepam	2759
T. Flunitrazepam	2763
U. Flurazepam	2767
V. Halazepam	2762
W. Haloxazolam	2771
X. Ketazolam	2772
Y. Loprazolam	2773
Z. Lorazepam	2885
AA. Lormetazepam	2774
BB. Mebutamate	2800
CC. Medazepam	2836
DD. Meprobamate	2820
EE. Methohexital	2264
FF. Methylphenobarbital (Mephobarbital)	2250
GG. Midazolam	2884
HH. Nimetazepam	2837
II. Nitrazepam	2834
JJ. Nordiazepam	2838
KK. Oxazepam	2835
LL. Oxazolam	2839
MM. Paraldehyde	2585
NN. Petrichloral	2591

OO. Phenobarbital	2285
PP. Pinazepam	2883
QQ. Prazepam	2764
RR. Quazepam	2881
SS. Temazepam	2925
TT. Tetrazepam	2886
UU. Triazolam	2887
VV. Zolpidem	2783

3. Fenfluramine. Any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position or geometric) and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible.

A. Fenfluramine 1670

4. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

A. Cathine (\pm)—norpseudoephedrine)	1230
B. Diethylpropion	1610
C. Fencamfamin	1780
D. Fenproporex	1575
E. Mazindol	1605
F. Mefenorex	1580
G. Pemoline (including organo-metallic complexes and chelates thereof)	1530
H. Phentermine	1640
I. Pipradrol	1750
J. SPA (-)-1-dimethylamino-1,2-diphenylethane	1635

5. Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

A. Pentazocine 9709

(E) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this subsection.

1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs and their salts:

A. Buprenorphine 9064

2. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient pro-

portion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

A. Not more than two and five-tenths milligrams (2.5 mg) of diphenoxylate and not less than twenty-five micrograms (25 μ g) of atropine sulfate per dosage unit.

B. Not more than one hundred milligrams (100 mg) of opium per one hundred milliliters (100 ml) or per one hundred grams (100 g).

C. Not more than five tenths milligram (0.5 mg) of difenoxin (DEA Drug Code No. 9618) and not less than twenty-five micrograms (25 μ g) of atropine sulfate per dosage unit.

3. Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including its salts, isomers and salts of isomers:

A. Pyrovalerone 1485

(2) Excluded Nonnarcotic Substances. The following nonnarcotic substances which, under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301), may be lawfully sold over the counter without a prescription are excluded from all schedules pursuant to section 195.015(5), RSMo.

**Excluded Nonnarcotic Products**

Company	Trade Name	NDC Code	Form	Controlled Substance	mg or mg/ml
Bioline Laboratories	Theophed	00719-1945	TB	Phenobarbital	8.00
Goldline Laboratories	Guiaphed Elixir	00182-1377	EL	Phenobarbital	4.00
Goldline Laboratories	Tedrigen Tablets	00182-0134	TB	Phenobarbital	8.00
Hawthorne Products, Inc.	Choate's Leg Freeze		LQ	Chloral hydrate	246.67
Parke-Davis & Co.	Tedral	00071-0230	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Elixir	00071-0242	EX	Phenobarbital	40.00
Parke-Davis & Co.	Tedral S.A.	00071-0231	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Suspension	00071-0237	SU	Phenobarbital	80.00
Parmed Pharmacy	Asma-Ese	00349-2018	TB	Phenobarbital	8.10
Rondex Labs	Azma-Aids	00367-3153	TB	Phenobarbital	8.00
Smith Kline Consumer	Benzedrex	49692-0928	IN	Propylhexedrine	250.00
Sterling Drug, Inc.	Bronkolixir	00057-1004	EL	Phenobarbital	0.80
Sterling Drug, Inc.	Bronkotabs	00057-1005	TB	Phenobarbital	8.00
Vicks Chemical Co.	Vicks Inhaler	23900-0010	IN	I-Desoxyephedrine	113.00
White Hall Labs	Primatene (P-tablets)	00573-2940	TB	Phenobarbital	8.00

AUTHORITY: section 195.195, RSMo Supp. 1993.* This rule was previously filed as 13 CSR 50-130.010 and 19 CSR 10-130.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed Oct. 4, 1972, effective Oct. 14, 1972. Amended: Filed April 4, 1973, effective April 14, 1973. Amended: Filed Sept. 28, 1973, effective Nov. 4, 1973. Amended: Filed Jan. 3, 1974, effective Jan. 13, 1974. Amended: Filed Oct. 9, 1974, effective Oct. 19, 1974. Amended: Filed July 17, 1975, effective July 27, 1975. Amended: Filed Oct. 8, 1975, effective Oct. 18, 1975. Refiled: March 24, 1976. Amended: Filed Oct. 12, 1976, effective Jan. 13, 1977. Amended: Filed March 15, 1977, effective March 24, 1977. Amended: Filed Nov. 14, 1977, effective Nov. 6, 1977. Amended: Filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed March 9, 1978, effective Feb. 24, 1978. Amended: Filed Oct. 2, 1978, effective Sept. 27, 1978. Amended: Filed Nov. 14, 1978, effective June 16, 1978. Amended: Filed Nov. 14, 1978, effective Oct. 25, 1978. Amended: Filed Feb. 13, 1979, effective Feb. 9, 1979. Amended: Filed Feb. 19, 1980, effective Feb. 11, 1980. Amended: Filed Oct. 14, 1980, effective July 24, 1980. Amended: Filed Oct. 14, 1980, effective Aug. 21, 1980. Amended: Filed Oct. 14, 1981, effective Oct. 30, 1980. Amended: Filed Oct. 14, 1981, effective May 8, 1981. Amended: Filed Oct. 14, 1981, effective Aug. 20, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Jan. 12, 1983, effective Feb. 11, 1983. Amended: Filed March 11, 1983, effective April 1, 1983. Amended: Filed Sept. 2, 1983, effective Dec. 11, 1983. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed July 12, 1984, effective Aug. 11, 1984. Amended: Filed Sept. 20, 1984, effective Nov. 11, 1984. Amended: Filed Jan. 15, 1985, effective Feb. 11, 1985. Amended: Filed May 29, 1985, effective June 27, 1985. Amended: Filed July 24, 1985, effective Aug. 26, 1985. Amended: Filed Sept. 12, 1985, effective Oct. 11, 1985. Changed to 19 CSR 10-130.010, effective Oct. 11, 1985. Amended: Filed Jan. 3, 1986, effective Jan. 16, 1986. Changed to 19 CSR 30-1.010, effective Aug. 11, 1986. Amended: Filed April 17, 1987, effective May 14, 1987. Amended: Filed July 3, 1987, effective Aug. 27, 1987. Amended: Filed May 3, 1988, effective May 26, 1988. Amended: Filed Sept. 25, 1989, effective Oct. 27, 1989. Emergency amendment filed April 3, 1991, effective April 13, 1991, expired Aug. 10, 1991. Emergency amendment filed May 1, 1991, effective May 11, 1991, expired Sept. 7, 1991. Emergency amendment filed July 23, 1991, effective Aug. 2, 1991, expired Nov. 28, 1991.

Amended: Filed April 3, 1991, effective Sept. 30, 1991. Amended: Filed May 1, 1991, effective Sept. 30, 1991. Amended: Filed March 2, 1992, effective Aug. 6, 1992. Amended: Filed July 6, 1993, effective Dec. 9, 1993. Emergency amendment filed Jan. 5, 1994, effective Jan. 15, 1994, expired May 14, 1994. Amended: Filed Jan. 5, 1994, effective July 30, 1994.

*Original authority 1957, amended 1971, 1989, 1993.

State v. Miller, 588 SW2d 237 (Mo. App. 1979). Evidence of the presence of amphetamine is sufficient to support a controlled substances conviction; no quantitative analysis is necessary. Those rules refiled between January 1 and March 31, 1976 were not required to be published under section 536.021, RSMo. Also, courts must take judicial notice of the contents of the *Code of State Regulations*.

Selvey v. State, 578 SW2d 64 (Mo. App. 1979). Phenmetrazine, originally established statutorily as a Schedule III controlled substance, was rescheduled by the Division of Health to Schedule II. Such a rescheduling is within the statutory power granted the Division of Health and does not usurp the legislative power of the general assembly.

State v. Davis, 450 SW2d 168 (Mo. App. 1970). Statutes which direct the Division of Health to prepare a list of drugs classified as barbiturates and stimulants, the sale of which are made unlawful by statute, does not violate the *Missouri Constitution* prohibition in Article I, section 31 against delegation of authority to an agency to make a rule fixing a fine or imprisonment as punishment for its violation.

19 CSR 30-1.020 List of Excepted Substances

PURPOSE: The Department of Health is authorized to except by rule any compound, mixture or preparation containing any stimulant or depressant substance if one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system is included to negate the potential for abuse. The compounds, mixtures and preparations excluded are listed in this rule.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material

will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) Excepted Stimulant or Depressant Compounds—Exempt Prescription Products. The listed drugs in dosage unit form and any other drug of the quantitative composition shown in Part 1300 to end of Title 21, the *Code of Federal Regulations*, April 1990 or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect and which are restricted by law to dispensing or prescription, are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.100, RSMo as provided for in section 195.017.6(5) and 8(3), RSMo.

(2) Excepted Chemical Preparations—Exempt Chemical Preparations. The listed preparations in unit form and any other preparation of the quantitative composition shown in Part 1300 to end of Title 21, the *Code of Federal Regulations*, April 1990 which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.110, RSMo as provided for in section 195.017.6(5) and 8(3), RSMo.

AUTHORITY: section 195.195, RSMo Supp. 1989.* This rule was previously filed as 13 CSR 50-130.020. Original rule filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed Nov. 14, 1978, effective Dec. 11, 1978. Amended: Filed Oct. 12, 1979, effective Nov. 11, 1979. Amended: Filed Oct. 14, 1981, effective Nov. 2, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed Oct. 2, 1991, effective Feb. 6, 1992.

*Original authority 1957, amended 1971, 1989.

19 CSR 30-1.025 List of Exempt Anabolic Steroid Products

PURPOSE: This rule maintains a list of anabolic steroid products excluded from 19 CSR 30-1.010(1)(C)5. in conformance with federal law.

(1) Persons who in the course of legitimate business handle products listed in the Table of Exempt Anabolic Steroid Products in this section shall be exempt from the registration, records, reports, prescriptions, physical security and import and export requirements associated with Schedule III substances.

(A) Trade Name	Company	NDC No.
1. Androgyn LA	Forest Pharmaceuticals, St. Louis, MO	0456-1005
2. Andro-EEstro 90-4	Rugby Laboratories, Rockville Center, NY	0536-1605
3. depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	0456-1020
4. DEPO-T.E.	Quality Research Pharmaceuticals, Camel, IN	52765-257
5. depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ	51698-257
6. Duomone	Wintec Pharmaceutical, Pacific, MO	52047-360
7. DURATESTRIN	W.E. Hauck, Alpharetta, GA	43797-016
8. DUO-SPAN II	Primedics Laboratories, Gardena, CA	0684-0102
9. Estratest	Solvay Pharmaceuticals, Marietta, GA	0032-1026
10. Estratest HS	Solvay Pharmaceuticals, Marietta, GA	0032-1023
11. PAN ESTRA TEST	Pan American Labs, Covington, LA	0525-0175
12. Premarin with Methyltestosterone	Ayerst Labs., Inc., New York, NY	0046-0879
13. Premarin with Methyltestosterone	Ayerst Labs., Inc., New York, NY	0046-0878
14. Synovex H Pellets in process	Syntex Animal Health, Palo Alto, CA	
15. Synovex H Pellets in process granulation	Syntex Animal Health, Palo Alto, CA	
16. Testagen Nashville, TN	Clint Pharmaceuticals,	55553-257
17. TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	0536-9470
18. Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate, Amityville, NY	0814-7737
19. Testosterone Cypionate-Estradiol Cypionate Injection	Best Generics, No. Miami Beach, FL	54274-530
20. Testosterone Cypionate-Estradiol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6611
21. Testosterone Cypionate-Estradiol Cypionate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0257

22. Testosterone Cypionate-Estradiol Cypionate Injection	Goldline Labs., Ft. Lauderdale, FL	0182-3069
23. Testosterone Enanthate-Estradiol Valerate Injection	Goldline Labs., Ft. Lauderdale, FL	0182-3073
24. Testosterone Enanthate-Estradiol Valerate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6618
25. Testosterone Enanthate-Estradiol Valerate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0360

AUTHORITY: section 195.015.4, RSMo Supp. 1989.* Original rule filed July 6, 1993, effective Dec. 9, 1993.

*Original authority 195.95.4, RSMo 1971, amended 1989.

19 CSR 30-1.030 Requirements for Controlled Substances Registration

PURPOSE: These rules provide effective controls on the manufacture, distribution, prescribing, dispensing and administration of narcotics and dangerous drugs in an effort to prevent them from being diverted from their intended uses to illicit markets, abuse and misuse.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) Registration and Reregistration.

(A) Fee Amounts. For each registration or reregistration to—

1. Manufacture controlled substances, the registrant shall pay an annual fee of two hundred dollars (\$200);

2. Distribute controlled substances, the registrant shall pay an annual fee of one hundred dollars (\$100);

3. Dispense controlled substances listed in Schedules II—V or to conduct research or instructional activities with those substances, the registrant shall pay an annual fee of thirty dollars (\$30);

4. Conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay an annual fee of thirty dollars (\$30);

5. Conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay an annual fee of thirty dollars (\$30); and

6. Import or export controlled substances listed in any schedule, the registrant shall pay an annual fee of one hundred dollars (\$100).

(B) Time and Method of Payment and Refunds. Registration and reregistration fees shall be paid at the time when the application for registration or reregistration is submitted for filing. Payment should be made in the form of a personal, certified or cashier's check or money order made payable to Department of Health. This is a nonrefundable processing fee. Payments made in the form of stamps, foreign currency or third-party endorsed checks will not be accepted.

(C) Persons Exempt From Fee. The Department of Health shall exempt the following persons from payment of a fee for registration or reregistration:

1. Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans Administration or Public Health Service who is authorized to procure or purchase controlled substances for official use;

2. Any official, employee or other civil officer or agency of the United States or state or any political subdivision or agency who is authorized to purchase controlled substances, to obtain these substances from official stocks, to dispense or administer these substances, to conduct research, instructional activities or chemical analysis with these substances, or any combination of them, in the course of his/her official duties or employment;

3. In order to claim exemption from payment of a registration or reregistration fee, the registrant shall apply for exemption by completing appropriate sections of the application; and

4. Exemption from payment of a registration or reregistration fee does not relieve the registrant of any other requirements or duties prescribed by law.

(D) Period of Registration.

1. At the time any person is first registered, s/he shall be assigned to one (1) of twelve (12) groups which shall correspond to the months of the year. The expiration date of the registrations of all persons within any group, will be the last day of the month designated for that group. In assigning any person to a group, the Department of Health may select a group, the expiration date of which is more than one (1) year from the date the person was registered.



2. The preceding initial fee schedule does not apply to manufacturers or distributors. These registrants will be registered on an annual basis only.

(E) Time for Application for Registration.

1. Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and certificate of registration is issued by the Department of Health to that person.

2. Application forms may be requested from—Missouri Department of Health, 1738 East Elm, Jefferson City, MO 65101.

3. Forms for renewal of registration will be sent to each registrant sixty (60) days prior to the expiration of the current registration.

(F) Separate Registration for Independent Activities. The following eight (8) groups of activities are deemed to be independent of each other and require separate registration:

1. Manufacturing controlled substances;
2. Distributing controlled substances;

3. Dispensing narcotic and nonnarcotic and conducting research with nonnarcotic and conducting instructional activities with narcotic and nonnarcotic controlled substances listed in Schedules II—V;

4. Conducting research with narcotic controlled substances listed in Schedules II—V;

5. Conducting research and instructional activities with controlled substances listed in Schedule I;

6. Conducting chemical analysis with controlled substances listed in any schedule;

7. Importing controlled substances; and
8. Exporting controlled substances listed in Schedules I—IV.

(G) Separate Registration for Separate Location. A separate registration is required for each principal place of business or professional practice at one (1) general physical location where controlled substances are manufactured, distributed or dispensed by a person.

1. The following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:

A. A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registrants other than the registered person or to persons not required to register;

B. An office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which

neither contains these substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

C. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at the office and where no supplies of controlled substances are maintained.

2. A separate registration is not required for each separate practice location for an individual practitioner who holds a Missouri professional practice license; is registered with the federal Drug Enforcement Administration (DEA); anticipates practicing in Missouri within the next twelve (12) months for no more than fourteen (14) days at more than one (1) location on a temporary basis and provides a statement outlining the location(s) and date(s) of that practice activity at the time of application; maintains a record of the date(s) and location(s) of all practice activity in Missouri and makes the record available to the Bureau of Narcotics and Dangerous Drugs; and prescribes but does not dispense or stock controlled substances at any Missouri practice location.

3. A controlled substance registration shall be issued for a Missouri practice location only.

(H) Application Information. All applicants shall make full, true and complete answers on the application. The Department of Health may require an applicant to submit documents or written statements of fact relevant to the application as considered necessary to determine whether the application should be granted. The failure of the applicant to provide these documents or statements within a reasonable time after being requested to do so shall be considered to be a waiver by the applicant of an opportunity to present these documents or facts for consideration in granting or denying the application.

(I) Modification in Registration. Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances by filing an application in the same manner as an application for new registration. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

(J) Termination of Registration. The registration of any person shall terminate if and when the person dies, ceases legal existence, discontinues business or professional practice or changes his/her name or address as shown

on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes his/her name or address as shown on the certificate of registration promptly shall notify the Department of Health of this fact. In the event of a change of name or address, the person may apply for a new certificate of registration in advance of the effective date of the change by filing an application and paying the appropriate fee in the same manner as an application for new registration. The application shall be handled in the same manner as an application for registration.

(K) Transfer of Registration. No registration or any authority conferred by registration shall be assigned or otherwise transferred.

(2) Requirements for the Physical Security of Controlled Substances by Registrants.

(A) Security Requirements Generally.

1. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in this section as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

2. Physical security controls shall be commensurate with the schedules and quality of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

3. All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

(B) Security Controls for Nonpractitioners.

1. Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the federal DEA or with the Department of Health to determine that the person is registered to possess the controlled substance.

2. The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

3. The registrant shall notify the Department of Health of any theft or significant loss of any controlled substances upon discovery of this theft or loss.

4. The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer and only in reasonable quantities. The request must contain the name, address and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements for order forms shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

(C) Physical Security Controls for Practitioners.

1. Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

2. Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may dispense these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

3. Subsection (2)(C) of this rule also shall apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(D) Other Security Controls for Practitioners.

1. The registrant shall not employ as an agent or employee who has access to controlled substances any person who has been found guilty or entered a plea of guilty or *nolo contendere* in a criminal prosecution under the laws of any state or of the United States for any offense related to controlled substances or who has had an application for a state or federal controlled substance registration denied or has had his/her registration revoked or surrendered for cause at any time. For purposes of this subsection, the term for cause means a surrender in place of or as a consequence of any federal or state adminis-

trative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

A. A registrant may apply in writing to the Department of Health for a waiver of paragraph (2)(D)1. of this rule for a specific employee.

B. The Department of Health may issue a written waiver to any registrant upon determination that a waiver would be consistent with the public health and safety. In making this determination, the Department of Health shall consider—the duties of the employee, the circumstances surrounding the conviction, the length of time since the conviction was entered, whether a waiver has been granted by the federal DEA to 21 CFR 1301.76, the security measures taken by the employer to prevent the theft and diversion of controlled substances, and any other factors consistent with public health and safety.

2. The registrant shall notify the Department of Health of the loss or theft of any controlled substances upon discovery of the loss or theft.

(3) Recordkeeping Requirements for Registrants.

(A) Definitions. As used in this rule, the following terms shall have the meanings specified:

1. The term commercial container means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user and, in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug or other package in which commercial containers are stored or are used for shipment of controlled substances;

2. The term dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance;

3. The term home infusion pharmacy means a pharmacy which compounds solutions for direct administration to a patient in a private residence, long-term care facility or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion;

4. The term individual practitioner means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not

include a pharmacist, a pharmacy or an institutional practitioner;

5. The term institutional practitioner means a hospital or other person (other than an individual) licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacy;

6. The term name means the official name, common or usual name, chemical name or brand name of a substance;

7. The term long-term care facility means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients;

8. The term pharmacist means any pharmacist licensed in Missouri to dispense controlled substances and shall include any other person (for example, pharmacist intern) authorized to dispense controlled substances under the supervision of a pharmacist licensed in Missouri;

9. The term prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.);

10. The term readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in a manner that they can be separated out from all other records in a reasonable time, records are kept on which certain items are asterisked, redlined or in some other manner visually identifiable apart from other items appearing on the records or a combination of these methods; and

11. Any term not defined in this section shall have the definition set forth in Chapter 195, RSMo.

(B) Persons Required to Keep Records.

1. Each registrant shall maintain the records and inventory required by section (3) of this rule except as exempted by section (3) of this rule.

2. Registered individual practitioners and institutional practitioners are required to keep records with respect to controlled substances listed in Schedule II which are prescribed and Schedules II—V controlled substances which are administered or dispensed.

3. A registered person using any controlled substance in research conducted in conformity with an exemption granted under Section 505(i) or 512(j) of the federal Food, Drug and Cosmetic Act (21 U.S.C. 355(i) or

360(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining these records.

4. A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to these substances is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining the records.

5. Notice required by paragraphs (3)(B)4. and 5. of this rule shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(C) Maintenance of Records and Inventories. Every inventory and other record required to be kept under section (3) of this rule, shall be kept by the registrant and be available, for at least two (2) years from the date of the inventory or record, for inspecting and copying by authorized employees of the Department of Health, except that financial and shipping records (such as invoices and packing slips, but not executed order forms) may be kept at a central location rather than at the registered location if the registrant obtains from the Department of Health approval of his/her central recordkeeping system and permit to keep central records. The permit to keep central records shall be subject to the following conditions:

1. The permit shall specify the nature of the records to be kept centrally and the exact location where the records will be kept;

2. The registrant agrees to deliver all or any part of these records to the registered location within forty-eight (48) hours of receipt of a written request from the Department of Health for these records and if the Department of Health chooses to do so in lieu of requiring delivery of records to the registered location, to allow authorized employees of the Department of Health to inspect the records at the central location upon request by the employees without a warrant of any kind; and

3. The failure of the registrant to perform his/her agreements under the permit shall revoke, without further action, the permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits under paragraph (3)(C)3. of this rule, the registrant, within thirty (30) days after the revocation,

shall comply with the requirement that all records be kept at the registered location.

(D) Each registered manufacturer, distributor, importer and exporter shall maintain inventories and records of controlled substances as follows:

1. Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

2. Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant.

(E) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in subsection (3)(D) of this rule.

(F) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy and prescriptions for these substances shall be maintained in a separate prescription file; and

2. Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in a form that the information required is readily retrievable from ordinary business records of the pharmacy and prescriptions for those substances shall be maintained either in separate prescription files for controlled substances listed in Schedules III, IV and V only or in a form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter C no less than one inch (1") high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances.

(G) General Requirements for Inventories.

1. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory was taken. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but

not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

2. A separate inventory shall be made by a registrant for each registered location in the event controlled substances are in the possession or under the control of the registrant at a location for which s/he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

3. A separate inventory shall be made by a registrant for each independent activity for which s/he is registered.

4. A registrant may take an inventory on a date that is within four (4) days of his/her biennial inventory date if, in advance, s/he notifies the Department of Health of the date on which s/he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

5. An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be transcribed promptly.

(H) Initial Inventory Date.

1. Every person required to keep records who is registered with the Department of Health after May 1, 1971 and who was not registered previously shall take an inventory of all stocks of controlled substances on hand on the date s/he first engages in the manufacture, distribution or dispensing of controlled substances.

2. Compliance with federal initial inventory date requirements is deemed satisfactory. Duplicate inventories are not required.

(I) Biennial Inventory Date. Every two (2) years following the date on which the initial inventory is taken by a registrant, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken on the date of the year on which the initial inventory was taken, on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than six (6) months from the biennial date that would otherwise apply or any other fixed date which does not vary by more than six (6) months from the biennial date that would otherwise apply. If the registrant elects to take the biennial

inventory on his/her regular general physical inventory date or another fixed date, s/he shall notify the Department of Health of this election and of the date on which the biennial inventory will be taken.

(J) Inventory Date for Newly Controlled Substances. On the effective date of a rule by the Department of Health adding a substance to any schedule of controlled substances, which substance was not listed immediately prior to that date in any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take inventory of all stocks of the substance on hand. After that, this substance shall be included in each inventory made by the registrant.

(K) Inventories of Manufacturers. Each registered manufacturer shall include the following information in his/her inventory:

1. For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in finished form, the name of the substance and the total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, *avoirdupois* weights may be utilized where metric weights are not readily available);

2. For each controlled substance in the process of manufacture on the inventory date the name of the substance, the quantity of the substance in each batch, stage of manufacture, or both, identified by the batch number or other appropriate identifying number and the physical form which the substance is to take upon completion of the manufacturing process (for example, granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number and if possible the finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number or volume;

3. For each controlled substance in finished form, the name of the substance; each finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four (4) one hundred (100) tablet bottles or three milliliter (3 ml) vials); the number of commercial containers of each finished form (for example, four (4) one hundred (100) tablet bottles or six (6) three milliliter (3 ml) vials); and

4. For each controlled substance not included in paragraphs (3)(K)1.—3. of this rule (for example, damaged, defective or

impure substances awaiting disposal, substances held for quality control purposes or substances maintained for extemporaneous compoundings), the name of the substance; the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; the reason for the substance being maintained by the registrant and whether the substance is capable of use in the manufacture of any controlled substance in finished form.

(L) Inventories of Distributors. Each registered distributor shall include in his/her inventory the same information required of manufacturers in paragraphs (3)(K)3. and 4. of this rule.

(M) Inventories of Dispensers and Researchers. Each person registered to dispense or conduct research with controlled substances and required to keep records shall include in his/her inventory the same information required of manufacturers in paragraphs (3)(K)3. and 4. of this rule. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

1. If the substance is listed in Schedule I or II, s/he shall make an exact count or measure of the contents; and

2. If the substance is listed in Schedule III, IV or V, s/he shall make an estimated count or measure of the contents, unless the container holds more than one thousand (1000) tablets or capsules in which case s/he must make an exact count of the contents.

(N) Inventories of Importers and Exporters. Each registered importer or exporter shall include in his/her inventory the same information required of manufacturers in paragraphs (3)(K)1., 3. and 4. of this rule. Each registered importer and exporter who also is registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that actually are separated from his/her stocks as a manufacturer or as a distributor (for example, in-transit or in storage for shipment).

(O) Inventories for Chemical Analysts. Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers in paragraphs (3)(K)1., 3. and 4. of this rule as to substances which have been manufactured, imported or received by the laboratory conducting the inventory. If less than one kilogram (1 kg) of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I) or less than twenty grams (20 g) of a hallucinogenic substance

listed in Schedule I (other than lysergic acid diethylamide) or less than point five gram (0.5 g) of lysergic acid diethylamide, is on hand at the time of inventory, those substances need not be included in the inventory. Laboratories of the division may process up to one hundred fifty grams (150 g) of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

(P) General Requirements for Continuing Records.

1. Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

2. Separate records shall be maintained by a registrant for each registered location except as provided in subsection (3)(C) of this rule. In the event controlled substances are in the possession or under the control of a registrant at a location for which s/he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

3. Separate records shall be maintained by a registrant for each independent activity for which s/he is registered.

4. In recording dates of receipt, importation, distribution, exportation or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (for example, invoices or packing slips).

(Q) Records of Manufacturers. Each registered manufacturer shall maintain records with the following information:

1. For each controlled substance in bulk form to be used in or capable of use in or being used in the manufacture of the same or other controlled or noncontrolled substances in finished form—

A. The name of the substance;

B. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

C. The quantity received from other persons including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

D. The quantity imported directly by the registrant (under a registration as an

importer) for use in manufacture by him/her, including the date, quantity and import permit or declaration number for each importation;

E. The quantity used to manufacture the same substance in finished form including the date and batch or other identifying number of each manufacture; the quantity used in the manufacture; the finished form (for example, ten milligram (10 mg) tablets or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units of finished form manufactured; the quantity used in quality control; the quantity lost during manufacturing and the causes for the loss, if known; the total quantity of the substance contained in the finished form; the theoretical and actual yields and other information as is necessary to account for all controlled substances used in the manufacturing process;

F. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subparagraph (3)(Q)1.E. of this rule;

G. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

H. The quantity exported directly by the registrant, including the date, quantity and export permit or declaration number of each exportation; and

I. The quantity distributed or disposed of in any other manner by the registrant (for example, distribution of complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity distributed or disposed; and

2. For each controlled substance in finished form—

A. The name of the substance;

B. Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial);

C. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required in subparagraph (3)(Q)1.E. of this rule;

D. The number of units of finished forms, commercial containers, or both, received from other persons, including the date of and number of units, commercial containers, or both, in each receipt and the

name, address and registration number of the person from whom the units were received;

E. The number of units of finished form, commercial containers, or both, imported directly by the registrant, including the date of and the number of units, commercial containers, or both, in each importation;

F. The number of units, commercial containers, or both, manufactured by the registrant from units in finished form received from others or imported including: the date and batch or other identifying number of each manufacture; the operation performed (for example, repackaging or relabeling); the number of units of finished form used in the manufacture, the number manufactured and the number lost during the manufacture, with the causes for these losses, if known, and other information as is necessary to account for all controlled substances used in the manufacturing process;

G. The number of commercial containers distributed to other persons including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

H. The number of commercial containers exported directly by the registrant, including the date, number of containers and export permit or declaration number for each exportation; and

I. The number of units of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity in finished form distributed or disposed.

(R) Records for Distributors. Each registered distributor shall maintain records with the following information for each controlled substance:

1. The name of the substance;

2. Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial);

3. The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

4. The number of commercial containers of each finished form imported directly by the registrant including the date of and the number of containers in each importation;

5. The number of commercial containers of each finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

6. The number of commercial containers of the finished form exported directly by the registrant, including the date of and the number of containers in each exportation; and

7. The number of units or volume of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution as complimentary samples) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

(S) Records for Practitioners and Researchers.

1. Each individual practitioner, institutional practitioner and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed or disposed:

A. The name of the substance;

B. Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial);

C. The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

D. The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed and the written or typewritten name or initials of the individual who dispensed or administered the substance; and

E. The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

2. Each individual practitioner shall maintain a record of the date, full name and address of the patient, the drug name, strength, dosage form and quantity for all Schedule II controlled substances prescribed and for all Schedule II—V controlled substances administered. This record may be maintained in the patient's medical record.

3. Individual practitioners shall maintain the records listed in subparagraphs (3)(S)1.A.—E. of this rule separately from patient medical records.

4. A registrant who transfers a controlled substance to or receives a controlled substance from another registrant shall maintain a written record of the transfer which contains the following information: the date of transfer, drug name, strength, dosage form, quantity, name, address and registration number of the transferring registrant and the name, address and registration number of the receiving registrant.

5. DEA Official Order Forms shall be used for transfers of Schedule II controlled substances.

6. A prescription may not be issued for an individual practitioner to obtain controlled substances for dispensing or administering to patients.

7. Prescriptions which are transmitted by facsimile to a pharmacy for dispensing shall include the telephone number of the facsimile machine or computer from which it is sent and the date and time of transmission. Immediately after a Schedule III, IV or V prescription or a Schedule II prescription for a long-term care facility patient or home hospice patient is transmitted to a pharmacy by facsimile equipment, the practitioner or the practitioner's agent shall sign and date the face of the prescription. The prescriptions shall be maintained in chronological order separately from patient files in a manner so each prescription is readily retrievable for inspection at the transmitting practitioner's office.

8. Any pharmacy receiving a controlled substance prescription transmitted by facsimile equipment shall maintain the facsimile copy of the prescription along with the date and time of transmission and the number of the facsimile machine from which it originated, as a part of its original prescription records.

9. Any practitioner who transmits a controlled substance prescription by electronic computer transmission shall maintain a printout of each day's transmissions. The practitioner shall verify that the information in the printout is correct and shall sign the printout.

10. Each pharmacist who dispenses controlled substances under a prescription sent

by electronic computer transmission shall verify with each practitioner on a regular basis that the prescription was authorized by the practitioner. If verification is made by telephone, the pharmacist shall document the verification on the reverse of the prescription or in the computer. If verification is made by sending the practitioner a copy of a computer printout, the practitioner shall verify, sign and return the printout to the pharmacy. The pharmacy shall maintain the verified printout in a separate file.

(T) Records for Importers. Each registered importer shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each importation;
3. The quantity (or number of units or volume in finished form) distributed to other persons, including the date, quantity (or number of units or volume) of each distribution and the name, address and registration number of each person to whom a distribution was made; and
4. The quantity disposed of in any other manner by the registrant except quantities used in manufacturing by an importer under a registration as a manufacture, which quantities are to be recorded, including the date and manner of disposal and the quantity disposed.

(U) Records of Exporters. Each registered exporter shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address and registration number of each person from whom the substance was received;
3. The quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume) and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacture, which quantities (and numbers of units and volumes) are to be recorded; and
4. The quantity disposed of in any other manner by the registrant including the date and manner of disposal and the quantity disposed.

(V) Records for Chemical Analysts.

1. Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him/her) for each controlled substance:

- A. The name of the substance;
- B. The form(s) in which the substance is received, imported or manufactured by the registrant (for example, powder, granulation, tablet, capsule or solution) and the concentration of the substance in that form (for example, Chemically Pure (CP), *United States Pharmacopeia* (USP), National Formulary (NF), ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per milliliter);
- C. The total number of the forms received, imported or manufactured (for example one hundred (100) tablets, thirty (30) one milliliter (1 ml) vials or ten grams (10 g) powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received; and
- D. The quantity distributed, exported or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

2. Order forms, import and export permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

3. Records of controlled substances used in chemical analysis or other laboratory work are not required.

4. Records relating to known or suspected controlled substances received as samples for analysis are not required under paragraph (3)(V)1. of this rule.

(W) Records for Long-Term Care Facility (LTCF) Emergency Kits. LTCFs and their suppliers shall maintain written records of transfers of controlled substances from the supplier to the LTCF emergency kit.

1. The records shall include the date of transfer; the name of each controlled substance, the strength, dosage form and quantity; the name, address and controlled substance registration number of the supplier and the name, address and controlled substance registration number of the LTCF. Federal DEA Official Order Forms shall not be used

to record transfers of controlled substances to LTCF emergency kits.

2. No physician's order or prescription shall be used for initial stocking or replacement of controlled substances in the emergency kit. Controlled substances contained in the kit shall be obtained from a pharmacy, hospital or practitioner who holds a controlled substances registration.

3. The administration and medical staff of the LTCF, in conjunction with the primary supplier, shall designate in written protocols and procedures who may have access to the emergency kit, who may administer controlled substances from the emergency kit and under what circumstances and a list of the controlled substances it intends to maintain in the emergency kit. These protocols and procedures shall be subject to review and approval by the Department of Health.

4. Each administration of controlled substances from the emergency kit shall be based upon a practitioner's order and shall be recorded in an administration record separate from the patient's medical record. This administration record shall include: the date, patient's name, drug name, drug strength, dosage, ordering practitioner's name and name of the person administering the controlled substance.

5. For the purpose of this subsection, the term LTCF means a nursing care, residential care, retirement care, mental care or other facility or institution which provides extended health care to resident patients and is licensed under Chapter 197 or 198, RSMo or operated by a state agency.

AUTHORITY: section 195.195, RSMo 1994. This rule was previously filed as 13 CSR 50-131.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed April 12, 1983, effective July 11, 1983. Amended: Filed May 31, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 26, 1991, effective April 9, 1992. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995.*

**Original authority 1957, amended 1971, 1989, 1993.*

MISSOURI DEPARTMENT OF HEALTH
ATTN: FEE RECEIPT UNIT
P.O. BOX 570
JEFFERSON CITY, MO 65102
MAIL ORIGINAL COMPLETED COPY
WITH \$25.00 FEE

MISSOURI DEPARTMENT OF HEALTH
BUREAU OF NARCOTICS AND DANGEROUS DRUGS
APPLICATION FOR MISSOURI
CONTROLLED SUBSTANCES REGISTRATION



REGISTRATION REQUIRED. INSTRUCTIONS FOR COMPLETION OF APPLICATION LOCATED ON BACK OF 2ND COPY.
PLEASE PRINT OR TYPE ALL ENTRIES. NO REGISTRATION MAY BE ISSUED UNLESS A COMPLETED APPLICATION FORM HAS BEEN RECEIVED.
RUBBER SIGNATURE STAMPS ARE NOT ACCEPTABLE. REVIEW COMPLETED APPLICATION BEFORE RETURNING WITH FEE TO THE ABOVE ADDRESS.
INCOMPLETE APPLICATION WILL BE RETURNED DELAYING PROCESSING.
WARNING: SECTION 195.040 RSMo, PROVIDES THAT THE REGISTRATION OF ANY PERSON WHO FURNISHES FALSE OR FRAUDULENT MATERIAL INFORMATION IN AN APPLICATION MAY BE DENIED, REVOKED OR SUSPENDED.

REGISTRANT NAME AND ADDRESS OF MISSOURI PRINCIPAL PLACE OF BUSINESS
(INCLUDE ZIP CODE)
1. _____
2. _____
3. _____
4. _____ CITY STATE ZIP CODE
5. _____

REGISTRATION CLASSIFICATION: SUBMIT CHECK OR MONEY ORDER PAYABLE TO THE MISSOURI DEPARTMENT OF HEALTH IN AMOUNT OF \$25.00 FEE MUST ACCOMPANY APPLICATION

1. BUSINESS ACTIVITY: (Check ONE only)
A RETAIL PHARMACY B HOSPITAL C PRACTITIONER
(Specify MD, DO, DDS, DMD, DVM, DPM, OD)
Nursing Home Kit KIT
Ambulance AMB
NTP Program NTP
D TEACHING INSTITUTION (Instructional purposes only)

2. DRUG SCHEDULES: (Check all applicable schedules in which you intend to handle controlled substances)
SCHEDULE II NARCOTIC SCHEDULE III NARCOTIC SCHEDULE IV NON-NARCOTIC SCHEDULE V NON-NARCOTIC

3. CHECK THIS BLOCK IF APPLICANT IS A LOCAL, STATE OR FEDERAL OFFICIAL OR INSTITUTION CLAIMING EXEMPTION FROM FEE. NAME OF GOVERNING UNIT: _____

4. PRACTITIONERS CHECK ALL BLOCKS THAT ARE APPLICABLE
 PRESCRIBE ACCEPT & DISPENSE SAMPLES DISPENSE

5. ALL APPLICANTS MUST ANSWER THE FOLLOWING:
A. Are you currently licensed and registered by the state to practice your profession under laws of this state? Enter Missouri professional license number, drug store permit number, hospital license number, etc. YES NO
B. Has the individual applicant or any officer of the corporate applicant or any individual employed by the applicant having access to controlled substances been convicted of any violation of any state or federal law relating to the possession, manufacture, distribution, dispensing or prescribing of narcotics or other controlled substances? If yes, give particulars on an attached sheet. YES NO
C. Has any previous state or federal controlled substances or narcotics registration or any state professional license or registration held by the applicant been surrendered, revoked, suspended, denied, restricted or placed on probation or is such action pending? If yes, give particulars on an attached sheet. YES NO
D. Enter Federal number that has been issued to you by the Drug Enforcement Administration _____
E. Enter business or office phone number _____

SIGNATURE OF INDIVIDUAL APPLICANT, OFFICER OF CORPORATE APPLICANT, HOSPITAL ADM. _____ OFFICIAL TITLE IF APPLICANT IS OTHER THAN AN INDIVIDUAL _____ DATE _____

**MISSOURI CONTROLLED SUBSTANCES
APPLICATION FOR REGISTRATION**

Instructions for Completing Form NDD 2A

PLEASE READ INSTRUCTION SHEET BEFORE COMPLETING FORM. ANY OMITTED INFORMATION WILL DELAY YOUR REGISTRATION.

ADDRESS BLOCK — Information must be **TYPED** or **PRINTED**. Only 5 lines of address are allowed. The manner in which this information is placed on the application is the way your certificate of registration will read. Please use the address of **proposed** office location. (Should be the address of Missouri principal office location.) (DO NOT USE P.O. BOX.) The address must correspond with the address provided on the federal DEA application.

PRACTITIONER: Line 1 — Last name, first name, middle name, professional degree; Lines 2, 3 and 4 — Street address; Line 5 — City, state and zip code.

RETAIL PHARMACY - HOSPITAL - OTHER - TEACHING INSTITUTION: Line 1 — Name of business or institution; Lines 2, 3, and 4 — Street address; Line 5 — City, state and zip code.

ITEM 1. BUSINESS ACTIVITY — Check only one class of business activity. A separate application and fee must be submitted for each business activity at the same or different locations. Also, if you desire to conduct any additional business activity shown in Section 1 of the form, you must submit a separate application and fee. Pay the fee as indicated in this section. Fee is non-refundable.

RETAIL PHARMACY: Name of pharmacy must appear in address block.

HOSPITAL: Applicants applying for hospital registration should check with local state licensing authority to be sure they meet state requirements for that activity. Hospital administrator must sign application.

PRACTITIONER: Please furnish medical degree in the space provided, next to practitioner business activity.

NOTE: Physicians with multiple office locations need only be registered at one of these locations unless controlled drugs will be stored or dispensed at each location; in that case, registrations are required at all locations.

NOTE: Registration is required to prescribe as well as dispense.

OTHER: Applicants for Nursing Home Emergency Kits, Ambulances and NTP Programs should check the block marked "OTHER" and specify "KIT," "AMB," or "NTP" in the block to the right.

TEACHING INSTITUTION: Registration as a teaching institution authorizes purchase and possession of controlled substances for instructional purposes only. Practitioners, teaching institutions or individuals within teaching institutions desiring to conduct research with any Schedule I substance, must obtain a "Researcher" registration by submitting Form NDD 2B with applicable fee.

ITEM 2. DRUG SCHEDULES — Retail pharmacies, hospitals, practitioners and teaching institutions are authorized to handle all schedules listed on the application. NTP programs should check only Schedule II Narcotic. Nursing home emergency kits and ambulances should check all schedules needed for the drugs they plan to carry. Note that Schedules II and III contain both narcotic and non-narcotic controlled substances. O.D.'s are limited to professional board protocols.

ITEM 3. EXEMPT OFFICIAL — Check only if your BNDD registration will be affiliated with federal, state or local government. The address on the application must be that of the affiliated federal, state or local government. The registration fee will not be required and Item 3A must be completed. A separate registration and payment of fee is required for business activities outside of official governmental duties.

ITEM 4. DISPENSING — Practitioners check each category which applies to your practice with controlled substances.

ITEM 5. STATE LICENSE AND SIGNATURE — A Missouri BNDD registration is based upon the applicant being in compliance with applicable state and local law. Possession of a current valid license to practice your profession or conduct your business is your authority to handle controlled substances. Applicants should contact the local state licensing authority prior to completing this application form. If state licensing authority is not applicable, complete with N/A. If you have applied for state license and it has not been issued, complete question 5A with "Pending." All applications will only be held in abeyance for 90 days. Questions 5B or C must be answered. If the question is not applicable, indicate N/A. If any of the questions 5B through E are answered "yes," attach a letter of explanation. Application must be signed and dated in INK. If you have applied for a Federal DEA number and it has not been issued, complete question 5D with "pending".

Upon receipt of an approved application and fee, a registration certificate will be prepared and sent to you.

THIS REGISTRATION CAN ONLY BE USED WITHIN THE SCOPE OF YOUR PROFESSIONAL PRACTICE.

NOTE: Once your BNDD registration is issued, a renewal application is automatically issued to you 60 days prior to your expiration date. In order to receive the renewal application, you must keep your registration address current, by notifying:

MISSOURI BUREAU OF NARCOTICS AND DANGEROUS DRUGS
P. O. BOX 570
JEFFERSON CITY, MISSOURI 65102

Address inquiries, questions, etc. to the above address.

19 CSR 30-1.033 Hearing Procedures on Controlled Substances Registration

PURPOSE: This rule provides procedures for Department of Health hearings to show cause why a controlled substances registration should not be denied, suspended or revoked.

(1) When the Department of Health holds a hearing under an order to appear for a hearing and show cause why a controlled substances registration should not be denied, suspended or revoked, the procedures of this rule shall be followed.

(2) Any person entitled to appear in a hearing may appear in person or by representative.

(3) Hearings shall be conducted in an informal but orderly manner under the direction of the presiding officer. Evidentiary rules do not apply.

(4) Participants in any hearing and their representatives shall conduct themselves in accordance with the directions of the presiding officer. Refusal to comply with this section shall constitute grounds for immediate exclusion from any hearing.

(5) A presiding officer, designated by the Department of Health, shall preside over the hearing. The functions of a presiding officer shall begin upon his/her designation and terminate upon certification of the record of the hearing to the Administrative Hearing Commission. The presiding officer shall conduct a fair and impartial hearing and take all necessary action to avoid delay and maintain order. The presiding officer shall have the authority to—

(A) Arrange and change the date, time and place of a hearing and issue notice of the change;

(B) Require parties to state their position in writing regarding issues in the hearing and to exchange statements with all other parties;

(C) Examine witnesses and direct witnesses to testify;

(D) Receive, rule on, exclude or limit evidence; and

(E) Rule on procedural issues.

(6) Any person entitled to a hearing who receives proper notice of the date, time and place of the hearing and fails to appear shall be considered to have waived his/her opportunity for the hearing, unless s/he shows a good reason for failing to appear. The presiding officer assigned to the case may issue a decision—without a hearing—on the basis of information in the investigative files and the allegations in the Department of Health's

order to show cause why a controlled substances registration should not be denied, suspended or revoked.

(7) At any hearing on the denial, suspension or revocation of a controlled substances registration, the registrant or applicant shall have the burden of proving that the requirements for registration have been satisfied.

(8) As soon as practicable after the hearing, the hearing officer shall issue a decision on the granting, denial, revocation or suspension of registration. If a registration is denied, revoked or suspended, the decision shall include the findings of fact and conclusions of law upon which the order is based. The decision shall specify the date on which it shall take effect. The hearing officer shall give one (1) copy of the decision to each party in the hearing.

(9) Hearings shall be recorded. Copies of the hearing record shall be made available to both parties upon request.

AUTHORITY: sections 195.040.11 and 195.195, RSMo Supp. 1989. Original rule filed Aug. 26, 1992, effective April 8, 1993.*

**Original authority: 195.040.11, RSMo 1939, amended 1971, 1978, 1987, 1989 and 195.195, RSMo 1957, amended 1971, 1989.*

19 CSR 30-1.035 Requirements for Prescribing, Dispensing and Administering Controlled Substances

PURPOSE: This rule provides effective controls for the prescribing, dispensing and administering of controlled substances to prevent diversion from lawful usage.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) As used in this rule, the following terms shall have the meanings specified:

(A) Home infusion pharmacy means a pharmacy which compounds solutions for direct administration to a patient in a private residence, long-term care facility or hospice setting by means of parenteral, intravenous,

intramuscular, subcutaneous or intraspinal infusion;

(B) Long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients; and

(C) Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

(2) When determining if controlled substances are being lawfully prescribed, dispensed and administered by practitioners, the Department of Health shall enforce Chapter 195, RSMo, the Department of Health rules in 19 CSR 30 pertaining to controlled substances, and the federal Controlled Substances Act 21 U.S.C. 801–966, and its regulations, 21 CFR 1300–1399. In determining lawful prescribing, dispensing and administering of controlled substances, the Department of Health also shall consider the provisions of Chapters 330, 332, 334, 336, 338 and 340, RSMo, the rules in 4 CSR 110, 4 CSR 150, 4 CSR 210, 4 CSR 220, 4 CSR 230 and 4 CSR 270, and protocols relating to the respective practitioners established and on file at the respective licensing boards.

(3) An individual practitioner who dispenses controlled substances shall—

(A) Provide direct supervision to employees or agents who assist in the dispensing of controlled substances. Controlled substances shall not be dispensed from an individual practitioner's inventory unless a practitioner is physically in the registered location except when a registered professional nurse is dispensing under a collaborative practice agreement;

(B) Package all controlled substances dispensed from an individual practitioner's inventory in compliance with the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471–1476;

(C) Permanently affix a label to the exterior of the drug container which includes: the date, the name and address of the dispensing practitioner, the name of the patient, directions for use, and the exact name and strength of the drug dispensed for all controlled substances dispensed; and

(D) Dispense only to individuals with whom the practitioner has established and

documented a practitioner/patient relationship. An individual practitioner shall not dispense under the order of another practitioner not practicing at that location.

(4) Controlled substances may be administered to a hospital emergency room patient under a verbal order of a registered practitioner who is not physically present if—

(A) The order is for a legitimate medical purpose and the practitioner who orders the administration of a controlled substance is acting in the usual course of his/her medical practice, after sufficient examination and establishment of a practitioner/patient relationship;

(B) The practitioner who orders the administration of a controlled substance is a medical staff member of the hospital;

(C) The administration of a controlled substance is documented in a formal medical record for the patient;

(D) The patient is assessed in the hospital by a practitioner, when available, or a registered nurse. If the patient is not assessed by a practitioner in the hospital, a registered nurse shall assess the patient and confirm and document in the patient's medical record the existence of a preestablished practitioner/patient relationship with the practitioner who ordered administration of a controlled substance; and

(E) The order is written in the patient's medical record and within seventy-two (72) hours, is authenticated by the ordering practitioner.

(5) A pharmacist may dispense directly a controlled substance in Schedule III, IV or V only under a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or his/her authorized agent or under an oral prescription made by an individual practitioner whether communicated by the practitioner or his/her authorized agent a prescription transmitted by electronic computer transmission by the authorizing practitioner or the practitioner's agent to the pharmacy. All oral prescriptions and prescriptions transmitted by electronic computer transmission shall be promptly reduced to writing by the pharmacist containing all information required in section 195.060, RSMo, except for the signature of the practitioner.

(6) A pharmacist may dispense a controlled substance in Schedule II only under a written prescription signed by the practitioner, except as provided in section 195.060.3, RSMo. A prescription for a Schedule II controlled substance may be transmitted from the prescrib-

ing practitioner to a pharmacy by facsimile equipment or electronic computer transmission, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except that—

(A) A prescription written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the home infusion pharmacy by facsimile. The facsimile shall serve as and shall be maintained in the same manner as an original written prescription.

(B) A prescription written for a Schedule II substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as and shall be maintained in the same manner as an original written prescription.

(7) All written controlled substance prescriptions shall be signed by the prescribing practitioner on the date prescribed. No controlled substance prescription shall be signed prior to the actual date it is issued.

AUTHORITY: sections 195.040.3(2), 195.050.6 and 195.195, RSMo 1994. Original rule filed Nov. 14, 1988, effective Feb. 24, 1989. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995.*

**Original authority: 195.040.3(2), RSMo 1939, amended 1971, 1978, 1987, 1989, 1994; 195.050.6, RSMo 1939, amended 1971, 1989; and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.036 Disposing of Unwanted Controlled Substances

PURPOSE: This rule establishes procedures for disposing of unwanted controlled substances.

(1) The following definitions shall be used in administering this rule:

(A) Controlled substances administration record—the form used to record information when administering individual drug doses to patients;

(B) Hospital—as defined in section 195.010(17), RSMo;

(C) Hospital employee—a nurse, physician, pharmacist or other responsible patient-care employee;

(D) Inventory record—the pharmacy record that documents the current inventory

level of controlled substances in the pharmacy;

(E) Nurse—registered or licensed practical nurse licensed under Chapter 335, RSMo; and

(F) Patient care areas—any area of a hospital where medical attention is rendered to a patient.

(2) A registrant in possession of any controlled substances and desiring or required to destroy the controlled substances beyond reclamation shall notify the Bureau of Narcotics and Dangerous Drugs (BNDD), the Drug Enforcement Administration (DEA) or other persons authorized by state or federal law or regulation to destroy controlled substances. If notification is to DEA, the federal procedures are to be followed. If notification is to the BNDD, the following procedures shall be used:

(A) Notification by the registrant shall consist of the name and address of registrant; registrant's BNDD and DEA number; the drug name, strength and amount to be destroyed; and

(B) The BNDD shall instruct the registrant to dispose of the controlled substance in one (1) of the following ways:

1. By delivery in person or registered mail to the BNDD office closest to the registrant;

2. By destruction at the registrant's work address by a BNDD employee or designee; or

3. By other means as the BNDD shall determine is sufficient to ensure that the substance will not become available to unauthorized personnel.

(3) In the event the registrant is a hospital, the following procedures are to be used for the destruction of controlled substances:

(A) When disposal of controlled substances is in patient care areas—

1. Controlled substances which are contaminated by patient body fluids are to be destroyed by a physician, nurse or a pharmacist in the presence of another hospital employee;

2. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;

3. The remaining contents of opened glass ampules of controlled substances shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;

4. Single units of single dose packages of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee or returned to the pharmacy for destruction;

5. The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substance administration or destruction records are to be retained for two (2) years and available for inspection by Department of Health investigators; and

6. All other controlled substances which are not patient contaminated but which are to be destroyed shall be returned to the pharmacy for destruction; and

(B) When disposal of controlled substances is in the pharmacy—

1. Single units of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a pharmacist in the presence of another hospital employee or held for later destruction; and

2. In the presence of the director or assistant director of security, or the director or assistant director of nursing, or the hospital administrator or assistant administrator, the director of pharmacy or designated pharmacist may destroy beyond reclamation any other unwanted controlled substances provided—the BNDD of the Department of Health is notified in writing by certified mail fifteen (15) calendar days prior to the proposed destruction date using the registrant's inventory of drugs destroyed or surrendered (Form NDD 12) stating the drug name and strength, the amount to be destroyed and the proposed destruction date and method of destruction. If the BNDD does not object, destruction shall occur on the proposed date. The pharmacist shall destroy the previously identified drugs, complete Form NDD 12 with the signature of the witness included and return a copy to the BNDD. The original shall be maintained at

the hospital for two (2) years with other controlled substances records.

(4) If the registrant administers controlled substances and is not a hospital, the following procedures are to be used for the destruction of controlled substances:

(A) Controlled substances which are contaminated by patient body fluids are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(B) An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use is to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(C) The remaining contents of opened glass ampules of controlled substances which are not patient contaminated are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(D) When the controlled substance is destroyed by the registrant or designee authorized to administer, the following shall be entered in the controlled substances administration records or a separate controlled substances destruction record: the date and amount destroyed, the reason for destruction and the registrant's name and address. The registrant or designee doing the destruction and the witnessing employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substances administration or destruction records are to be retained for two (2) years and available for inspection by Department of Health investigators; and

(E) All other controlled substances which are not patient-contaminated but are to be destroyed shall be placed in a suitable container for storage, and the BNDD notified of the need for destruction.

AUTHORITY: section 195.050.6, RSMo 1986. Original rule filed Jan. 18, 1989, effective April 27, 1989.*

**Original authority 1939, amended 1971, 1989.*



MISSOURI DEPARTMENT OF HEALTH
BUREAU OF NARCOTICS AND DANGEROUS DRUGS

P.O. BOX 570
JEFFERSON CITY, MO 65102

REGISTRANTS INVENTORY OF DRUGS DESTROYED OR SURRENDERED

PAGE OF

REGISTRANT'S NAME		MISSOURI CONTROLLED SUB. NO.	FEDERAL DEA NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)			
SIGNATURE OF REGISTRANT OR AUTHORIZED AGENT			DATE
DRUG OR SUBSTANCE NAME AND STRENGTH	NUMBER OF TABS, CAPS, ETC.	DRUG OR SUBSTANCE NAME AND STRENGTH	NUMBER OF TABS, CAPS, ETC.
The following is an inventory of scheduled drugs and substances which have been (Check one) <input type="checkbox"/> Destroyed on the premises. <input type="checkbox"/> Surrendered for proper disposition. <input type="checkbox"/> Sealed and retained on premises.			
		BNDD REPRESENTATIVE	DATE

MO 580-0171 (7-89)

DISTRIBUTION: WHITE - REGISTRANT; CANARY - BNDD CENTRAL OFFICE; PINK - BNDD OFFICE

NDD-12 (R7-89)



MISSOURI DEPARTMENT OF HEALTH
BUREAU OF NARCOTICS AND DANGEROUS DRUGS

P.O. BOX 570
JEFFERSON CITY, MO 65102

REGISTRANT'S INVENTORY OF DRUGS DESTROYED (HOSPITAL)

PAGE ____ OF ____

REGISTRANT'S NAME	MISSOURI CONTROLLED SUB. NO.	FEDERAL DEA NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)		

The following inventory of controlled substances is proposed for destruction according to 19 CSR 30-1.036 Disposing of Controlled Substances.

PROPOSED DESTRUCTION DATE	PROPOSED DESTRUCTION METHOD(S)
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SIGN HERE BEFORE SENDING COPY TO BNDD.		SIGNATURE OF AUTHORIZED AGENT
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TITLE	SUBSTANCE NAME AND STRENGTH	DOSAGE FORM	UNIT OR PACKAGE NAME	UNIT OR PKG. SIZE	DATE	NO. OF UNITS OR PKGS
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

- Cross out unused spaces.
 - All information must be legible or procedure is void.
- The above inventory of controlled substances has been destroyed beyond reclamation in my presence.**

SIGNATURE OF AUTHORIZED AGENT 	TITLE	DATE
SIGNATURE OF AUTHORIZED WITNESS (SEE 19 CSR 30-1.036) 	TITLE	DATE

- Each page must be signed.
- Form may be copied.

DISPOSING OF UNWANTED CONTROLLED SUBSTANCES IN HOSPITALS

The Missouri Department of Health, Bureau of Narcotics and Dangerous Drugs (BNDD) has implemented a regulation (19 CSR 30-1.036) establishing procedures for controlled substance destruction. Because of the special needs of hospitals, a section of the regulation provides specific procedures for destruction in hospitals. It gives authority for traditional destruction in patient care areas with certain limitations and requirements, and allows destruction of bulk quantities in the pharmacy after proper notification to BNDD and with proper witnessing.

PROCEDURE FOR DESTRUCTION IN THE HOSPITAL PHARMACY

1. Use Form NDD-12A, Registrant's Inventory of Drugs Destroyed (Hospital). Photocopies of this form are acceptable.
2. Complete Form NDD-12A and sign and date the top of the form.
3. Send a copy of Form NDD-12A by certified mail to the Bureau of Narcotics and Dangerous Drugs, Box 570, Jefferson City, MO 65102.
4. Destroy drugs by pharmacist and witness (see regulation for authorized witnesses) on the proposed date if certified mail return receipt has been received, unless BNDD requests you to hold the destruction.
5. Pharmacist and witness sign and date Form NDD-12A.
6. Send copy of signed Form NDD-12A to BNDD and retain original with controlled substances records for two years.

Additional Guidelines

1. Forms which are not properly completed will be returned, and destruction cannot occur.
2. The proposed destruction date must be at least 15 days after BNDD receives notification.
3. All information must be legible.
4. Do not "write over" for changes in amounts. Draw a line through the incorrect amount, write in the correct amount and initial the change.
5. Include dosage unit strength or concentration.
6. Include strength or concentration of each controlled substance in non-proprietary combination products.
7. Describe dosage form as tablet, syrup, injection, etc.
8. Describe unit or package name as ampul, syringe, IV bag, etc., where appropriate to identify certain packages.
9. "Cross out" all unused spaces on the form. Do not add additional items after proposed copy has been sent.
10. Number pages consecutively.
11. After destruction, pharmacist and witness sign each page.
12. A copy of the signed form must be sent to BNDD.
13. BNDD will forward a copy to the Drug Enforcement Administration.

PATIENT'S OWN PRESCRIPTION CONTROLLED SUBSTANCES

The hospital should have a policy for handling the patient's personal property, including prescriptions. There is no authority for a hospital to receive controlled substances from a patient for disposal. When a hospital inadvertently comes into possession of a patient's controlled substance prescription and wishes to dispose of it, the same procedure may be used as for the hospital's own unwanted controlled substances. These may NOT be included in the hospital's inventory of controlled substances, and records should be clearly identified and maintained separately from the hospital's records of its own controlled substances. If Form NDD-12A is used, it should be marked "Patient's Own Drugs", and the following information included: patient name, labeled drug name and strength, quantity, prescription number, and dispensing pharmacy.

Please refer to the regulation for complete destruction authorizations and restrictions. Please call 314-751-6400 for clarification or additional information.

MO 580-1537 (12-92)



MISSOURI DEPARTMENT OF HEALTH
BUREAU OF NARCOTICS AND DANGEROUS DRUGS

AN EQUAL OPPORTUNITY/AFFIRMATIVE ACTION EMPLOYER
services provided on a nondiscriminatory basis

REGISTRANT'S INVENTORY OF DRUGS DESTROYED (HOSPITAL)
(This form may be used only for succeeding pages to NDD-12A)

PAGE _____ OF _____

1	SUBSTANCE NAME AND STRENGTH	DOSAGE FORM	UNIT OR PACKAGE NAME	UNIT OR PKG. SIZE	NO. OF UNITS OR PKGS.
2					
3					
4					
5					
6					
7					
8					
9					
10					
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17					
18					
19					
20					
21					
22					

The above inventory of controlled substances has been destroyed beyond reclamation in my presence.

SIGNATURE OF AUTHORIZED AGENT

TITLE

DATE

SIGNATURE OF AUTHORIZED WITNESS (SEE 19 CSR 30-1.036)

TITLE

DATE

- Each page must be signed.
- Form may be copied.

19 CSR 30-1.040 Dispensing and Distribution of Controlled Substances in Certain Situations

PURPOSE: These rules provide for the dispensing of Schedule V controlled substances, for the dispensing of Schedule II controlled substances in emergency situations and for the emergency distribution of a controlled substance.

(1) Emergency Dispensing of Schedule II Controlled Substances. In the case of a bona fide emergency situation, as defined by the Department of Health, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner; provided, that—

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription;

(B) The prescription immediately shall be reduced to writing by the pharmacist and shall contain all information, except for the prescribing practitioner's signature;

(C) If the prescribing practitioner is not known to the pharmacist, s/he must make reasonable effort to determine that the oral authorization came from a practitioner, by verifying his/her phone number against that listed in the directory and other good faith efforts to insure his/her identity; and

(D) Within seventy-two (72) hours after authorizing an emergency oral prescription, the prescribing practitioner must cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face authorization for emergency dispensing. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be post-marked within the seventy-two (72)-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Department of Health if the prescribing practitioner fails to deliver a written prescription to him/her; failure of the pharmacist to do so shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

(2) Definition of Emergency Situation. For the purpose of authorizing an oral prescription of a controlled substance listed in Schedule II of the controlled substances law (sec-

tions 195.010–195.320, RSMo), the term emergency situation means those situations in which the prescribing practitioner determines that—

(A) Immediate administration of a controlled substance is necessary for proper treatment of the intended ultimate user;

(B) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II; and

(C) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

(3) Emergency Controlled Substance Distribution by a Pharmacy. An emergency means a situation where a quantity of a controlled substance must be dispensed by a pharmacy to a patient who does not have an alternative source for that substance reasonably available to him/her and the pharmacy cannot obtain that substance through its normal distribution channels within the time required to meet the immediate needs of the patient for that substance. In the event of an emergency, a pharmacy may distribute (without being registered as a distributor) a controlled substance in Schedule III, IV or V to a second pharmacy in order for that pharmacy to dispense the substance; provided, that—

(A) The amount distributed does not exceed the amount required by the second pharmacy for his/her immediate dispensing;

(B) The distribution is recorded as being dispensed by the first pharmacy and the second pharmacy records the substance as being received. Each pharmacy will retain a signed receipt of the distribution;

(C) The second pharmacy is registered to dispense the controlled substance to be distributed to him/her; and

(D) If the substance is a Schedule II controlled substance, an order form is required.

(4) Dispensing of Schedule V Substances, Requirement of Prescription.

(A) A pharmacist directly may dispense a controlled substance listed in Schedule V pursuant to a prescription. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription. If this authorization is given, the prescription may not be refilled. A pharmacist dispensing those substances pursuant to a prescription shall label the substance and file the prescription.

(B) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule V in the course of

his/her professional practice without a prescription.

(C) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required except for the signature of the prescribing individual practitioner) or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(5) Dispensing Without Prescription. A controlled substance listed in Schedule V which is not a prescription drug and determined under the federal Food, Drug and Cosmetic Act may be dispensed by a pharmacist without a prescription to a purchaser at retail; provided, that—

(A) Dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his/her professional and legal responsibilities, the actual cash transaction, credit transaction or delivery may be completed by a nonpharmacist);

(B) Not more than two hundred forty cubic centimeters (240 cc) eight ounces (8 oz.) of any controlled substance containing opium, nor more than one hundred twenty cubic centimeters (120 cc) four ounces (4 oz.) of any other controlled substance nor more than forty-eight (48) dosage units of any controlled substance containing opium, nor more than twenty-four (24) dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48)-hour period;

(C) The purchaser is at least eighteen (18) years of age;

(D) The pharmacist requires every purchaser of a Schedule V controlled substance not known to him/her to furnish suitable identification (including proof of age where appropriate);

(E) A bound record book for dispensing of Schedule V controlled substances is maintained by the pharmacist. The book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with recordkeeping requirements); and



(F) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law.

AUTHORITY: section 195.195, RSMo 1986.
This rule was previously filed as 13 CSR 50-132.010. Original rule filed Jan. 31, 1972, effective April 1, 1972.*

**Original authority 1957, amended 1971, 1989.*